STATE OF MICHIGAN

DEPARTMENT OF LABOR & ECONOMIC GROWTH

OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX
Petitioner **File No. 90456-001**

v

Aetna Life Insurance Company
Respondent
_____/

Issued and entered
this 18th day of August 2008
by Ken Ross
Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On June 18, 2008, XXXXX (Petitioner) filed a request for external review with the Commissioner of the Office of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* After a preliminary review of the material submitted the Commissioner accepted the request on June 25, 2008.

The case presented a medical question so the Commissioner assigned it to an independent review organization (IRO), which provided its analysis to the Commissioner on July 8, 2008.

II
FACTUAL BACKGROUND

The Petitioner has group health care coverage through XXXXX that is underwritten by Aetna Life Insurance Company (Aetna) and was effective March, 2, 2007. His health care benefits are defined in the certificate of coverage (the certificate) issued by Aetna.

On January 8, 2008, the Petitioner had tests, including a blood test to check his homocysteine level. A claim was submitted for payment but Aetna denied coverage for the

homocysteine test on the basis that it was experimental or investigational for treatment of his condition.

The Petitioner appealed through Aetna's internal grievance process and received its final adverse determination letter dated June 3, 2008.

III
ISSUE

Is Aetna correct in denying coverage for the homocysteine test provided on January 8, 2008?

IV
ANALYSIS

Petitioner's Argument

On January 5, 2008, the Petitioner presented to the hospital emergency room with chest pains. He was admitted overnight to rule out a myocardial infarction. He followed up with his physician on January 7, 2008, who suspected he may have had a heart attack. The physician ordered several tests, including the homocysteine test that was done on January 8, 2008. Aetna denied coverage for the test on the basis that it was experimental or investigational for assessing coronary heart disease (CHD) or stroke risk.

The Petitioner argues that the test was necessary to determine if he had a cardiac problem. He assumed the test was done to decide if he had a pulmonary embolism. He therefore believes Aetna should cover the test.

Aetna Life Insurance Company's Argument

Aetna says that the Petitioner's claims were processed according to the terms of his certificate. The certificate includes the following under the section entitled "General Exclusions" on pages 23-24:

> Coverage is not provided for the following charges:
>
> * * *
>
> - Those for or in connection with services or supplies that are, as determined by Aetna, to be experimental or investigational. A drug, a

> device, a procedure, or treatment will be determined to be experimental or investigational if:
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> > there are insufficient outcomes data available from controlled clinical trials published in the peer reviewed literature to substantiate its safety and effectiveness for the disease or injury involved; or
> >
> > if required by the FDA, approval has not been granted for marketing; or
> >
> > a recognized national medical or dental society or regulatory agency has determined, in writing, that it is experimental, investigational, or for research purposes; or
> >
> > the written protocol or protocols used by the treating facility, or the protocol or protocols of any other facility studying substantially the same drug, device, procedure, or treatment, or the written informed consent used by the treating facility or by another facility studying the same drug, device, procedure, or treatment states that it is experimental, investigational, or for research purposes.

Aetna concedes that the homocysteine test is appropriate for certain purposes but says it considers the test as experimental or investigational for assessing CHD or stroke risk because the peer-reviewed medical literature has not demonstrated the efficacy of the test for the Petitioner's diagnosis. Because it considers the Petitioner's homocysteine test to be experimental or investigational, Aetna concluded that it was not a covered benefit.

Commissioner's Review

The Petitioner's certificate says that experimental or investigational services are excluded from coverage. In reviewing adverse determinations that involve issues of whether a service is investigational or experimental, the Commissioner requests an analysis and recommendation from an IRO. The IRO expert reviewing this case is certified by the American Board of Internal Medicine with a subspecialty in cardiovascular disease, published in peer-reviewed medical literature, and in active practice.

The IRO report said in part:

> Based on the limited documentation submitted for review, it is the determination of this reviewer that the Homocysteine blood level testing is considered investigational/experimental.

> The purpose of homocysteine testing in [the Petitioner] was to employ it as a "nontraditional" measure of cardiac risk and consider lowering the level if it was elevated. The use of homocysteine levels in actual patient care should be predicated on:
>
> 1. An ability to classify those who are truly at risk and those who are not
> 2. A plausible biological mechanism
> 3. Demonstration that lowering homocysteine levels lowers cardiac risks
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> Initially, as assortment of retrospective and prospective studies suggested a strong association between elevated homocysteine levels and cardiac risk…. * * * Recent investigations of the concept of independent risk factors in ischemic heart disease would find such a weak association highly questionable or not clinically useful. Relative risk is poorly related to ability to classify patients into groups consisting of those who are truly at risk and those who are not.
>
> * * *
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> Thus it can be seen that homocysteine levels are only weakly associated with coronary risk and cannot be used to accurately classify patients into "at risk" or "not at risk" categories. * * *
>
> Therefore, the significance of a homocysteine level in [the Petitioner] is of uncertain clinical meaning and the use of such levels must be considered investigational/experimental.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner because it is based on extensive expertise and professional judgment. The Commissioner can discern no reason why the IRO recommendation should be rejected in the present case. Therefore, the Commissioner accepts the conclusions of the IRO reviewer and finds that the Petitioner's homocysteine test is experimental or investigational for his condition and is not a covered benefit.

The Commissioner finds that Aetna correctly applied the provisions of the certificate.

V
ORDER

The Commissioner upholds Aetna Life Insurance Company's final adverse determination of June 3, 2008. Aetna is not required to provide coverage for the Petitioner's homocysteine test on January 8, 2008.

This is a final decision of an administrative agency. Under MCL 550.1915, any person

aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.